

Summary

Proactive Safety Management in Health Care Towards a Broader View of Risk Analysis, Error Recovery, and Safety Culture

Medical errors occur frequently. The harm and additional costs associated with those errors ask for effective safety management. According to the objective of minimal patient harm, safety management in health care should be proactive; that is, risks should be anticipated and reduced *before* patients are harmed. However, until recently, health care organisations particularly used reactive approaches. Not until errors happened and harm was caused, did they conduct risk analyses. Because such a reactive safety management approach is insufficient, the research reported in this dissertation aimed to contribute to the understanding of proactive safety management. This dissertation presents six studies that dealt with the main research question: “*How could health care organisations apply proactive safety management to prevent patient harm and minimise costs of poor safety?*”. Together, the studies addressed three distinct but complementary approaches towards proactive safety management: (1) conducting and integrating prospective and retrospective risk analyses (*methods*), (2) obtaining information about error recovery (*data*), and (3) improving on safety culture (*organisational context*).

In the first study (Chapter 2), a qualitative field study, the application of the prospective risk analysis method Healthcare Failure Mode and Effect Analysis (HFMEA™) was evaluated in Dutch health care. In an HFMEA™ analysis, a multidisciplinary team identifies and assesses potential risks in a selected health care process and determines actions

to eliminate or reduce those risks. In total, 13 HFMEA™ analyses were conducted. User feedback has revealed benefits and drawbacks regarding HFMEA™. Benefits were the systematic approach, the multidisciplinary nature of the analysis, and the fact that the analysis yielded a clear understanding of the process itself, the accompanying tasks, as well as the potential risks. Drawbacks were related to the risk assessment part of HFMEA™ (i.e. the rating scales and the decision tree) and the time investment needed to conduct the analysis. In sum, this study has shown that HFMEA™ can successfully be applied in health care, but also that the method can be improved, for instance by customising the rating scales.

The second study (Chapter 3), a qualitative field study on two units of a Dutch general hospital, concentrated on the triangulation and integration of prospective and retrospective methods for risk analysis, which is important because both methods are subject to biases. In the prospective analyses, a condensed version of HFMEA™ was used for the identification and assessment of risks in selected processes. In the retrospective analyses, incidents were reported by employees and subsequently investigated. The methods were integrated by making use of information from retrospective incident reports for prospective risk identification and assessment, and by matching their categorisation schemes. Results indicated that the two analyses yielded divergent overviews of risks. Two evaluation forms, filled out by employees, showed that the combination of prospective and retrospective analyses provided additional insight into risks. Thus, this study has demonstrated that triangulation of prospective and retrospective methods can provide a more complete and reliable picture of risks. Furthermore, integration of the two methods could be advantageous in terms of efficiency of analysis, setting priorities, and improving the methods themselves.

The third study (Chapter 4) addressed the order of implementation of prospective and retrospective methods and its influence on incident reporting behaviour. A quasi-experimental field study was conducted on 12 units of two Dutch general hospitals. A reversed-treatment non-equivalent control group design was used to test the hypotheses that had been formulated. The six units of Hospital 1 first carried out a prospective risk analysis (an adapted version of HFMEA™), after which a sophisticated retrospective incident reporting and analysis system was introduced. On the six units of Hospital 2, the two methods were implemented in reverse order. Data from the incident reporting and analysis system and from evaluation forms showed that carrying out a prospective analysis *first* (i.e. *before* introducing a sophisticated incident reporting and analysis system) did improve incident reporting behaviour in terms of a wider spectrum of reported incident types and a larger proportion of incidents reported by doctors. However, the proposed order did not necessarily yield a larger number of reported

incidents. Overall, this study has shown that health care organisations can use prospective methods to enhance incident reporting behaviour.

The fourth study (Chapter 5), a qualitative field study, concentrated on error recovery, which is important since errors are unavoidable and cannot be completely prevented by error reduction strategies. There appeared to be a need for a clearer and more consistent definition of near misses to enable their large-scale reporting and analysis. By means of incident reports and interviews on four units of two Dutch general hospitals, information about error handling was collected. Analysis of 143 error handling processes has revealed that different incident types each provide unique information about the way errors are detected and dealt with. Two possible definitions of near misses have been proposed and it has been argued that the optimal definition may well be contingent on organisational context.

In the fifth study (Chapter 6), also a qualitative field study, it was argued that besides information about *successful* error recovery, information about *unsuccessful* error recovery can also be used to develop strategies that promote people's abilities to recognise and intercept errors in time. In total, 52 medication errors (that all resulted in severe patient harm or patient death, i.e. accidents) were analysed to reveal failed, missed and absent error recovery opportunities. The results have indicated that, in addition to near misses, accidents can be used as a data source to obtain information about error recovery as well.

The sixth study (Chapter 7) was a longitudinal panel survey, in which it was proposed that a positive safety culture can be essential for proactive safety management. A culture in which safety is considered a top priority, could enhance safety behaviour and performance and can promote the success of prospective and retrospective methods for risk analysis. In a panel survey among 701 health care employees of three Dutch hospitals, the trends in safety culture were evaluated after an extensive safety management programme had been implemented. The use of self-reported safety culture surveys as an evaluation instrument could be questioned because only a few significant changes were identified. Nevertheless, the observed positive trends regarding incident reporting behaviour, response to errors, and management support are promising. Further, the results have shown that incident reporting behaviour is positively associated with feedback about and learning from errors, handoffs and transitions, as well as teamwork. In case of effective feedback and learning mechanisms and good teamwork (including smooth shift changes), health care employees are thus more likely to report errors.

To conclude, three distinct but complementary approaches to proactive safety management have been proposed in this dissertation. A culture in which safety is deemed of

utmost importance and people are preoccupied with risks is essential for proactive safety management. Critical assessment of processes can be useful to identify and eliminate risks before errors may occur. If errors do crop up, a vigilant attitude of health care employees can enhance timely error recognition and correction, as a result of which patient harm can still be averted. In case of errors, people should anyhow be willing to report them to share lessons and facilitate organisational learning. Such a proactive approach towards safety management could improve patient safety, minimise patient harm, and limit costs of poor safety. In conclusion, proactive safety management is important for those people who find that patient safety is a moving target.